



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA-2015-N-3785]

Medical Devices; Orthopedic Devices; Classification of Posterior Cervical Screw Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to classify posterior cervical screw systems into class II (special controls) and to continue to require premarket notification to provide a reasonable assurance of safety and effectiveness of the device. A posterior cervical screw system is a prescription device used to provide immobilization and stabilization in the cervical spine as an adjunct to spinal fusion surgery. The term "posterior cervical screw systems" is used to distinguish these devices from currently classified pedicle screw spinal systems cleared for use in other spinal regions.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-3785 for "Medical Devices; Orthopedic Devices; Classification of Posterior Cervical Screw Systems." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Genevieve Hill, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1457, Silver Spring, MD 20993-0002, 301-796-6423, [genevieve.hill@fda.hhs.gov](mailto:genevieve.hill@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

#### A. Statutory and Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential

unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the issue of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), as "preamendments devices." Under section 513(d)(1) of the FD&C Act, FDA classifies these devices after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III and devices found to be substantially equivalent by means of premarket notification procedures (510(k)) to such a preamendments device or to a device within that type without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the

FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

FDA refers to devices that were not in commercial distribution prior to May 28, 1976 as "postamendments devices." These devices are automatically classified by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

#### B. Regulatory History of the Device

The regulatory history of posterior cervical screw systems arose from that of pedicle screw spinal systems, which are medical devices similar in design and principle of operation, but differ based on anatomic use in the spine and their indications for use. Both device systems are comprised of various interconnecting components such as longitudinal members (i.e., rods, plates) and screws that are configured per the patient's anatomy and implanted into the posterior spine to provide stabilization as bony fusion occurs. After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices, in accordance with section 513(b) of the FD&C Act. In the Federal Register of September 4, 1987 (52 FR 33686), FDA classified a total of 77 generic types of orthopedic devices. Neither pedicle screw spinal systems nor posterior cervical screw systems were identified in this initial effort.

In July 1998, FDA issued a final rule (63 FR 40025, July 27, 1998) classifying pedicle screw spinal systems as class II devices, and a technical amendment to this rule was published on May 22, 2001 (66 FR 28051). In the technical amendment, FDA noted that pedicle screw systems for the following intended uses in the cervical spine (which are now referred to as posterior cervical screw systems) were in use prior to May 28, 1976 and are therefore considered preamendments devices: (1) Cervical spondylolisthesis (all grades and types); (2) cervical spondylolysis; (3) cervical degenerative disc disease; (4) degeneration of the cervical facets accompanied by instability; (5) cervical trauma (fracture and dislocation); and (6) revision of failed previous fusion surgery (pseudarthrosis) of the cervical spine. Since 2001, FDA has regulated posterior cervical screw systems as unclassified preamendments devices requiring premarket notification (510(k)). Posterior cervical screw systems currently on the market have been determined to be substantially equivalent to devices that were in commercial distribution prior to May 28, 1976.

On April 9, 2009, FDA published an order under sections 515(i) and 519 of the FD&C Act (515(i) order) for the submission of safety and effective information on pedicle screw spinal systems with certain indications for use (74 FR 16214). In response to that order, FDA received a request from the Orthopedic Surgical Manufacturers Association (OSMA) to classify posterior cervical screw systems into class II (special controls). Because this request was considered to be outside the scope of the 515(i) order related to pedicle screw spinal systems, FDA requested that OSMA submit a separate petition for classification of posterior cervical screw systems. OSMA submitted the requested petition on November 22, 2011, under Docket No. FDA-2011-P-0851-0001/CCP (Ref. 1). FDA consulted with the Orthopaedic and Rehabilitation Devices Panel (the Panel), an FDA advisory committee, regarding the classification of this device type on

September 21, 2012 (Ref. 2). At the Panel meeting, the Panel recommended that posterior cervical screw systems be classified as class II with special controls.

## II. Recommendation of the Panel

During a public meeting held on September 21, 2012, the Panel made recommendations regarding the classification and regulatory controls for posterior cervical screw systems.

### A. Identification

FDA is proposing the following identification for posterior cervical screw systems based on the Panel's recommendations and the Agency's review. Posterior cervical screw systems utilizing pedicle and lateral mass screws, implanted from the C1 to C7 levels, are multiple component devices, made from a variety of materials, including metallic alloys. Posterior cervical instrumentation generally involves use of a fixation system comprised of both longitudinal members and screws that can span various combinations of spinal levels from the occiput to the upper thoracic spine. Cervical lateral mass and pedicle screws serve as the primary bone anchor points and require selection based on individual patient anatomy, as determined by preoperative cross-sectional imaging. Posterior cervical screw systems consist of a bone anchor via screws (i.e., occipital screws, cervical lateral mass screws, cervical pedicle screws, C2 pars screws, C2 translaminar screws, C2 transarticular screws), longitudinal members (e.g., plates, rods) and optional transverse connectors. An interconnection mechanism (e.g., offset connector, nuts, screws, or bolts) may be utilized to link the anchor and longitudinal member. These posterior cervical screw systems are statically fixed devices, only intended to be used as an adjunct to fusion and do not include any dynamic features, which may include, but are not limited to: Non-uniform and/or non-metallic longitudinal elements, features that allow more motion or flexibility compared to traditional rigid systems, or features that do not provide the



system immediate rigid fixation.

### B. Recommended Classification of the Panel

The Panel recommended that posterior cervical screw systems be classified into class II (special controls).

### C. Summary of Reasons for Recommendation

The Panel considered the panel members' personal knowledge of and clinical experience with the device type, as well as the history of safety and effectiveness of the device over many years of clinical use. The Panel recommended that posterior cervical screw systems be classified into class II as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine and craniocervical junction: (1) Traumatic spinal fractures and/or traumatic dislocations; instability or deformity; (2) failed previous fusions (e.g., pseudarthrosis); (3) tumors involving the cervical spine; and (4) degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Panel also found that there is reasonable evidence to support use of posterior cervical screws as an adjunct to fusion in the pediatric population. In addition, there was panel consensus supporting the use of posterior cervical screws for non-fusion treatment for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion; the Panel emphasized that their discussions were limited to this narrow patient population and should not be extrapolated to other non-fusion applications or

technologies (e.g., dynamic stabilization systems).

The Panel also recommended that posterior cervical screw systems be classified into class II because special controls, together with general controls, would provide reasonable assurance of their safety and effectiveness. The risks to health for this device type are known and can be adequately mitigated by special controls (such as mechanical testing, biocompatibility, and labeling).

#### D. Risks to Health

Based on the Panel's discussion and recommendations in addition to comprehensive literature reviews and analyses by OSMA and FDA, the risks to health associated with posterior cervical screw systems and the proposed measures to mitigate these risks are identified in the following list and in table 1. The identified risks to health are identical to those proposed by FDA during the September 21, 2012, panel meeting, with the addition of risks associated with the presence of vertebral arteries, as recommended by FDA with panel agreement. FDA determined that the following risks to health are associated with its use:

- Device failure--Components may deform, fracture, wear, loosen, or disassemble, resulting in a mechanical or functional failure.
- Failure at the bone/implant interface--Components may loosen or disengage from the bone.
- Tissue injury--Intraoperative and postoperative risks of tissue injury include: Bone fracture, injury to blood vessels or viscera, neurologic injury, dural tear or cerebrospinal fluid leak, skin penetration or irritation, and postoperative wound problems, including infection, hematoma/seroma.

- Adverse tissue reactions--Adverse tissue reactions include: Foreign body response, metal allergy, and metal toxicity.
- Device malposition--Risks of device malposition may include difficulty or inability to implant the device components or incorrect placement of the device.
- Pseudarthrosis--The risk of nonunion, or pseudarthrosis, signifies failure of bony fusion and potential instability or pain.
- Adverse clinical sequelae--Adverse clinical sequelae may include the risk of new or unresolved neck pain, new or worsened neurologic deficit/injury, or loss of correction.

The risks to health presented to the 2012 Panel such as cardiac, respiratory, and death are considered general surgical risks associated with the surgical procedure to implant posterior cervical screw systems; these risks are not directly associated with posterior cervical screw systems and therefore are not included in the previous list of risks. Failure of the posterior cervical screw system as a result of the risks to health listed may result in the need for reoperation, revision, or removal.

While presented to the Panel as a potential risk, graft settling would not be considered a device-specific risk. Rather, it represents a potential mechanism for the development of pseudarthrosis, instability, or lack of correction. Further, graft settling is expected in patients undergoing fusion surgery and does not necessarily result in adverse clinical sequelae. Thus this item does not specifically appear in the previous list.

#### E. Proposed Special Controls

FDA believes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health described in section II.D. and provide reasonable assurance of safety and effectiveness of the device.

- Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
- Nonclinical performance testing must demonstrate the mechanical function and durability of the implant.
- Device must be demonstrated to be biocompatible.
- Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.
- Labeling must bear all information required for the safe and effective use of the device, specifically including the following:
  - Clear description of the technological features of the device, including identification of device materials and the principles of device operation;
  - intended use and indications for use including levels of fixation;
  - device-specific warnings, precautions, and contraindications that include the following statements:
    - "Precaution: Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered.

In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary."

- "Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels."
- identification of magnetic resonance (MR) compatibility status;
- cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
- detailed instructions of each surgical step, including device removal, accompanied by magnified illustrations.

Table 1 summarizes the risks to health described in section II.D. and the proposed special controls that are sufficient to mitigate these risks.

Table 1.--Summary of Risks to Health and Proposed Special Controls

Risk to Health	Method of Mitigation (i.e., Special Control)
Device Failure	Design Characteristics Nonclinical Performance Testing Labeling
Failure of Bone Implant Interface	Design Characteristics Biocompatibility Nonclinical Performance Testing Labeling
Tissue Injury	Labeling
Adverse Tissue Reactions	Design Characteristics Biocompatibility Sterility Labeling
Device Malposition	Labeling
Pseudarthrosis	Nonclinical Performance Testing Biocompatibility Labeling
Adverse Clinical Sequelae	Labeling

Furthermore, FDA is proposing that posterior cervical screw systems be prescription devices. Prescription devices must be used in accordance with 21 CFR 801.109. Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

### III. Proposed Classification and FDA's Finding

In preparation for the September 2012 panel meeting and to better inform the Agency's proposed classification of posterior cervical screw systems as described in this proposed rule, FDA conducted a review of the literature that included relevant scientific and medical information published through July 2012 (see Section 6 of FDA's Panel Executive Summary, Ref. 2) as well as adverse events in FDA's Manufacturer and User Facility Device Experience (MAUDE) database (see Section 7 of FDA's Panel Executive Summary, Ref. 2). FDA does not believe that new or different information has become available since the September 2012 panel meeting that would alter FDA's findings. Based upon FDA's review of the literature and adverse events and FDA's continued premarket and postmarket experience with the device type, FDA agrees with the Panel's recommendation that posterior cervical screw systems be classified into class II. FDA is proposing to classify these devices into class II because general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of these implantable devices (see section II.D.), as presented and discussed during the September 21, 2012, panel meeting (Ref. 2). FDA also believes there is sufficient information to establish special controls to mitigate the known risks of the device. Therefore, FDA proposes that posterior cervical screw systems be classified into class II. The special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

#### IV. Proposed Effective Date

FDA proposes that this proposed rule, if finalized, will become effective 30 days after its date of publication in the Federal Register. In addition, FDA proposes that once the final rule is in effect, manufacturers of posterior cervical screw systems as defined in section II.A. that have not been offered for sale prior to the effective date of the final rule must obtain 510(k) clearance before marketing their devices and comply with the special controls.

FDA notes that a firm who markets a device that is intended for use as a posterior cervical screw system as identified in section II.A., as well as other uses, that was legally in commercial distribution before May 28, 1976, or who markets a device found to be substantially equivalent to such a device and who does not intend to market such device for uses other than as a posterior cervical screw as defined in section II.A., may remove the other intended uses from the device's labeling and continue marketing the device without submitting a new 510(k). In addition, such posterior cervical screw systems must comply with the special controls.

#### V. Environmental Impact, No Significant Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because: (1) The proposed regulation would classify a previously unclassified preamendment device type; (2) only five registered establishments are listed in the Establishment Registration and Device Listing database that would be affected by the proposed rule; and (3) the proposed regulation designating the classification of posterior cervical screw systems as class II is consistent with the historical regulatory oversight given to this device type, we proposed to certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule proposes to classify posterior cervical screw systems as class II devices with special controls. These devices are currently unclassified. Currently, manufacturers are subject to premarket requirements similar to class II devices, with producers receiving clearance to



market via a 510(k) premarket notification submission without a PMA requirement. We have concluded that special controls in addition to general controls are sufficient for ensuring the safety and effectiveness of these devices and that these devices may be classified as class II (special controls).

FDA's Registration and Listing database identifies two large manufacturers of three posterior cervical screw systems (product code NKG). Manufacturers of these devices will need to edit any current labeling to reflect requirements of the proposed rule. This is considered a major label change because of the addition of precaution statements. The estimated cost of this labeling change is \$13,189 per product for an estimated total cost of \$39,567 ( $3 \times \$13,189$ ). Any currently marketed devices seeking marketing authorization as posterior cervical screw systems would incur similar costs. We welcome comments on the number of applications we may receive from firms pursuing marketing authorization for currently marketed products as posterior cervical screw systems.

The proposed rule would require that manufacturers who wish to market these devices submit 510(k) premarket notifications and comply with the proposed special controls. It is not expected that manufacturers of devices already on the market would need to submit new 510(k) notifications, 510(k) amendments, or add-to-files to demonstrate conformance with the proposed special controls. Any manufacturers seeking marketing authorization of posterior cervical screw systems would not incur additional costs as a result of this rule because we already require 510(k) submissions for these devices. Hence, the proposed rule would not result in any significant change in how manufacturers prepare 510(k) submissions for the affected devices or in how we would review the submissions. Consequently, compliance with the special controls proposed for these devices would not yield significant new costs for manufacturers. Because the

formal classification of the affected devices as class II is consistent with current Agency and industry practice, we conclude that the proposed rule, if finalized, would not impose any significant additional regulatory burden.

We invite comments on this analysis.

## VII. Paperwork Reduction Act of 1995

This proposed rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910-0625. The precaution labeling provisions in proposed 21 CFR 888.3075(b)(5) are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the following labeling: (1) "Precaution: Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary." (2) "Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the

proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels." are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

## VIII. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Orthopedic Surgical Manufacturers Association Reclassification Petition filed on November 23, 2011, to support classification of pedicle and lateral mass screws for cervical spine use from unclassified status to class II. Available at [www.regulations.gov](http://www.regulations.gov), the docket number is FDA-2011-P-0851.

2. Transcript and other meeting materials from the Food and Drug Administration Orthopedic Devices Panel Meeting, September 21, 2012, (<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm309184.htm>).

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 888 as follows:

### PART 888--ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 888.3075 to subpart D to read as follows:

§ 888.3075 Posterior cervical screw system.

(a) Identification. Posterior cervical screw systems, implanted from the C1 to C7 levels, are prescription devices comprised of multiple components, made from a variety of materials, including metallic alloys. Posterior cervical instrumentation generally involves use of a fixation system comprised of both longitudinal members and screws that can span various combinations of spinal levels from the occiput to the upper thoracic spine. Cervical lateral mass and pedicle screws serve as the primary bone anchor points and require selection based on individual patient anatomy, as determined by preoperative cross-sectional imaging. Posterior cervical screw systems consist of a bone anchor via screws (i.e., occipital screws, cervical lateral mass screws, cervical pedicle screws, C2 pars screws, C2 translaminar screws, C2 transarticular screws), longitudinal members (e.g., plates, rods) and optional transverse connectors. An interconnection mechanism (e.g., offset connector, nuts, screws, or bolts) may be utilized to link the anchor and longitudinal member. These posterior cervical screw systems are intended to provide immobilization and stabilization of spinal segments (C1 to C7 levels) in patients as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine and/or craniocervical junction and/or cervicothoracic junction: Traumatic spinal fractures and/or traumatic dislocations; spinal deformities and related instabilities; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; inflammatory disorders; degenerative disease, including neck and/or arm pain of discogenic origin as confirmed by radiographic studies; degenerative disease of the facets with instability; and reconstruction following decompression to treat intractable radiculopathy and/or myelopathy. These systems are also

intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

(b) Classification. Class II (special controls). The special controls for posterior cervical screw systems are:

(1) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(2) Nonclinical performance testing must demonstrate the mechanical function and durability of the implant.

(3) Device must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.

(5) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) Clear description of the technological features of the device including identification of device materials and the principles of device operation;

(ii) Intended use and indications for use including levels of fixation;

(iii) Device specific warnings, precautions, and contraindications that include the following statements:

(A) "Precaution: Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the

placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary."

(B) "Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels."

(iv) Identification of magnetic resonance (MR) compatibility status;

(v) Sterilization and cleaning instructions for devices and instruments that are provided non-sterile to the end user, and;

(vi) Detailed instructions of each surgical step, including device removal, accompanied by magnified illustrations.

Dated: March 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-05384 Filed: 3/9/2016 8:45 am; Publication Date: 3/10/2016]